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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,555	10/31/2003	Roland Christof Hutter	21686-US	9951

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Roche Molecular Systems, Inc.
Patent Law Department
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EXAMINER	
BOWERS, NATHAN ANDREW	

ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
05/24/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/698,555	HUTTER ET AL.	
	Examiner	Art Unit	
	NATHAN A. BOWERS	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-18 and 20-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-18 and 20-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *031110*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 9-13, 17, 18, 20, 21 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaami (US 20010016321) in view of Barbera-Guillem (US 20040029266) and Lehmann (US 1161984).

With respect to claim 9, Tanaami discloses a reaction vessel for processing a biological sample. The reaction vessel comprises a tubular body (Figure 5:12) having a bottom wall, an upper opening and sidewalls. A chip shaped carrier (Figure 5:16) having an active surface formed by a plurality of biopolymers (Figure 5:CL21-CL23) is located on the inner surface of the tubular sidewall. This is disclosed in paragraphs [0024]-[0026]. The bottom walls and sidewalls form a straight tubular chamber for receiving a liquid and for interacting with a needle. Paragraphs [0026]-[0029] state that the needle (Figure 6:18) is pushed through a rubber plug (Figure 6:13) that seals the top opening of the tube during the delivery of a fluid. Although Tanaami states that the chamber is adapted for receiving the needle, Tanaami does not expressly indicate that the rubber plug and tube upper opening are likewise adapted for receiving a pipetting tip.

Barbera-Guillem discloses a reaction vessel (Figure 1:100) for processing a biological sample. Paragraphs [0226]-[0228] state that a fluid inlet opening is covered by a rubber septum (Figure 1:230) designed to interact with either a pipetting tip or a needle. Paragraph [0246] discloses a specific embodiment in which the reaction vessel septum is designed to interact with a cannula needle (Figure 23:C) attached to the end of a pipette (Figure 23:P) so that the needle is used as the pipetting tip.

Tanaami and Barbera-Guillem are analogous art because they are from the same field of endeavor regarding biological sample processing vessels.

At the time of the invention, one of ordinary skill in the art would have found it obvious to use a needle at the end of the pipette disclosed by Tanaami or a pipetting tip

capable of puncturing the rubber seal like a needle. Paragraphs [0226]-[0228] of Barbera-Guillem indicate that needles and pipette tips are functionally equivalent fluid delivery means in that each can be effectively pushed through a solid barrier in order to access the interior of a vessel. Accordingly, one of ordinary skill would have known to swap the needle of Tanaami for a pipetting tip since both are fully capable of penetrating a rubber seal. Paragraph [0246] of Barbera-Guillem further suggests that it alternatively would have also been obvious to simply attach the needle of Tanaami to the end of a pipetting tool when adding fluid to the tubular body. This would have been beneficial because pipetting devices are well known in the art as effective means by which do deliver a precise quantity of fluid.

The combination of Tanaami and Barbera-Guillem still differs from Applicant's claimed invention because Tanaami does not expressly state that the chip shaped carrier is located in either an opening of a tube side wall or in a recess formed within the inner surface of a tube side wall.

Lehmann discloses a reaction vessel for processing a biological sample contained in a liquid. The vessel includes a body (Figure 1:15) having a bottom wall, an upper opening (Figure 1:13), and sidewalls which extend between the bottom wall and the upper opening. The bottom wall and the sidewalls form a chamber (Figure 5:33) for receiving a liquid to be processed. A chip shaped carrier (Figure 2:21) having an active surface (Figure 2:32) is accessible to liquid contained in the chamber. The chip shaped

carrier is located in an opening (Figure 2:18) in the sidewall of the body. This is disclosed in paragraphs [0021]-[0025], [0032] and [0033].

Tanaami and Lehmann are analogous art because they are from the same field of endeavor regarding biological sample processing reaction vessels that comprise an internal chip shaped carrier.

At the time of the invention, it would have been obvious to provide the chip shaped carrier disclosed by Tanaami either within an opening of the tube side wall or within a recess formed in the interior surface of the tube side wall. As evidenced by Lehmann, this configuration is considered to be well known in the art. Paragraphs [0044]-[0047] state that the positioning of a biochip within the side wall surface of a reaction vessel can be carried out using known techniques quickly and easily using an automated instruments. Placement of the Tanaami chip within an opening or depression formed within a side wall would require only a minor structural alteration, that, as evidenced by Lehmann, would be completed in a highly predictable manner.

With respect to claim 10, Tanaami, Barbera-Guillem and Lehmann disclose the reaction vessel in claim 9 wherein the tubular body is configured and dimensioned such that, when the chip shaped carrier is contacted with a liquid, an air space exists between the free surface of the liquid and the upper opening. Although Tanaami does not clearly describe these limitations, the disclosed device is configured and dimensioned in such a way that it is capable of fulfilling these requirements. This is apparent from Figure 5.

With respect to claim 11, Tanaami, Barbera-Guillem and Lehmann disclose the reaction vessel in claim 9. Furthermore, the chip shaped carrier of Tanaami is located at a predetermined distance fro the bottom wall and from the upper opening of the tubular body.

With respect to claims 12 and 13, Tanaami, Barbera-Guillem and Lehmann disclose the reaction vessel in claim 9 wherein the chip shaped carrier is transparent. In paragraph [0030], Tanaami teaches that the biopolymers immobilized upon the carrier are optically evaluated using a light source and a detector. Figure 5 indicates that the excitation light and emission light are moved through the body of the carrier, as well as through the sidewall of the tubular chamber.

With respect to claims 22 and 23, Tanaami, Barbera-Guillem and Lehmann disclose the reaction vessel in claim 9. Tanaami further states that the vessel further comprises a cap (figure 5:13) for removably closing the opening. The rubber plug cap is configured and dimensioned such that a part thereof may cooperate with the gripper of a transport mechanism.

With respect to claim 24, Tanaami, Barbera-Guillem and Lehmann disclose the reaction vessel in claim 9. The only opening disclosed by Tanaami is the upper opening of the tubular body.

With respect to claims 17, 18, 20 and 21, Tanaami, Barbera-Guillem and Lehmann disclose the apparatus set forth in claim 9 as set forth in the 35 U.S.C. 103 rejection above, however do not provide specific dimensions describing the volume of the reaction chamber or the shape of the carrier chip. Regardless, it would have been obvious to ensure that the chamber had a width of at least 1.5 mm and an inner volume of 10-800 microliters if it was determined that these dimensions produced the most effective size. This is especially true because these measurements approach those of common test tubes already well known in the art. Reaction chamber side lengths are considered result effective variables that are optimized through routine experimentation. Furthermore, it would have been obvious to ensure that the carrier chip had a side length between 2 to 10 mm. A chip of these dimensions would be large enough to be easily micromachined using known techniques, but small enough to fit within a common test tube. At the time of the invention, it would have been apparent to fashion the reaction chamber disclosed by Tanaami according to the specifications presented in claims 17, 18, 20 and 21 if it was determined that these measurements allowed the device to function at an optimum level.

2) Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaami (US 20010016321) in view of Barbera-Guillem (US 20040029266), Lehmann (US 1161984) and Lary (US 4845025).

Tanaami, Barbera-Guillem and Lehmann disclose the combination as previously described above, however, do not expressly indicate that the vessel is in

communication with a vessel holder capable of moving along a predetermined elliptical trajectory.

Lary discloses a system from processing a test tube (Figure 15:24) in which a reaction vessel is coupled to a vessel holder in the form of a mixing arm (Figure 15:52). Figures 15 and 16 and column 7, line 59 to column 8, line 13 state that the mixing arm is moved along a predetermined elliptical trajectory for causing mixing of fluids within the vessel.

Lehmann and Lary are analogous art because they are from the same field of endeavor regarding reaction vessels.

At the time of the invention, it would have been obvious to utilize a moving means such as described by Lary to influence mixing within the reaction vessel disclosed by Tanaami. It is well established in the art that mixing means are beneficial because they allow one to provide effective contact between the sample solution and the active surface of the chip shaped carrier. The specific mixing mechanism of Lary is advantageous because it is highly reproducible, inexpensive, and more reliable than other mixing devices that are based on liquid circulation via pumping.

3) Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaami (US 20010016321) in view of Barbera-Guillem (US 20040029266), Lehmann (US 1161984) and Lary (US 4845025) as applied to claim 5, and further in view of Frackleton (US 5133937).

Tanaami, Barbera-Guillem, Lehmann and Lary disclose the apparatus set forth in claim 5 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly indicate that a heat transfer element is provided for heating and cooling the contents of the reaction vessel.

Frackleton discloses a system for processing a biological sample contained in a liquid. Frackleton teaches that a reaction vessel (Figure 1:90) is coupled to a vessel holder (Figure 1:30) that comprises various heat transfer elements (Figure 1:62 and Figure 1:124). This is described in column 3, line 12 to column 4, line 48.

Tanaami and Frackleton are analogous art because they are from the same field of endeavor regarding biological sample processing devices.

At the time of the invention, it would have been obvious to incorporate heat transfer elements in the system disclosed by Tanaami. In column 1, lines 14-18, Frackleton indicates that biological analytical reactions are frequently temperature sensitive, and therefore require accurate temperature control. The heating and cooling mechanisms described by Frackleton are considered to be well known in the art.

4) Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaami (US 20010016321) in view of Barbera-Guillem (US 20040029266) and Lehmann (US 1161984) as applied to claim 9, and further in view of Frackleton (US 5133937).

Tanaami, Barbera-Guillem and Lehmann disclose the apparatus set forth in claim 9 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly indicate

that a heat transfer element is provided for heating and cooling the contents of the reaction vessel.

Frackleton discloses a system for processing a biological sample contained in a liquid. Frackleton teaches that a reaction vessel (Figure 1:90) is coupled to a vessel holder (Figure 1:30) that comprises various heat transfer elements (Figure 1:62 and Figure 1:124). This is described in column 3, line 12 to column 4, line 48.

At the time of the invention, it would have been obvious to ensure that the device disclosed by Tanaami was capable of interacting with various heat transfer elements. In column 1, lines 14-18, Frackleton indicates that biological analytical reactions are frequently temperature sensitive, and therefore require accurate temperature control. The heating and cooling mechanisms described by Frackleton are considered to be well known in the art.

5) Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaami (US 20010016321) in view of Barbera-Guillem (US 20040029266) and Lehmann (US 1161984) as applied to claim 9, and further in view of Mochida (GB 2129551).

Tanaami, Barbera-Guillem and Lehmann disclose the apparatus set forth in claim 9 as set forth in the 35 U.S.C. 102 rejection above, however do not expressly indicate that the sidewalls carry a barcode label.

Mochida discloses the use of immunoassay vessels (Figure 1:1) that utilize barcode labels (Figure 1:2) as a tracking mechanism. This is disclosed on page 3, lines 60-64.

Tanaami and Mochida are analogous art because they are from the same field of endeavor regarding biological analysis devices.

At the time of the invention, it would have been obvious to include a bar code label on the outer sidewalls of the reaction vessel disclosed by Tanaami. Bar codes are helpful in quickly sorting and tracking reaction vessels, and they can be used to immediately determine the identity of a specified reaction vessel in the presence of a plurality of otherwise identical reaction vessels, thus reducing confusion and the occurrence of mistakes.

Response to Arguments

Applicant's arguments filed 11 March 2010 with respect to the 35 U.S.C. 103 rejection involving Tanaami, Barbera-Guillem and Lehmann have been fully considered but they are not persuasive.

Applicant's principle arguments are

(a) A needle is not and cannot be assimilated to a pipetting tip. A pipetting tip cannot pierce a rubber plug, and therefore pipetting operations are not possible in Tanaami without removing the rubber plug.

In response, please consider the following remarks.

Barbera-Guillem is provided as evidence that pipetting tips are used in the art to pierce a rubber seal in order to deliver fluid to a reaction container. In paragraphs [0225]-[0228], Barbera-Guillem states that the rubber septum is punctured using either a pipetting tip or a needle. Barbera-Guillem also indicates that needles can be used in

combination with a pipetting device to deliver a fluid. This is set forth in paragraph [0246] and in Figure 23. Accordingly, it would have been obvious to utilize the Tanaami needle as a pipetting tip.

It is noted that Applicant additionally argues that Barbera-Guillem does not disclose the use of a needle, but rather a pipetting tip with a needleless connector. Assuming, *arguendo*, that Applicant's reading is correct, it must be concluded that pipetting tips and needles are functionally equivalent. If Barbera-Guillem fails to disclose a needle, the pipette tip must be used to directly pierce the septum (i.e. rubber plug). Accordingly, the pipette tip is utilized just as if it were a piercing needle.

In addressing Applicant's dictionary definitions of pipetting tip and needle, it is understood that both read on slender, hollow, narrow tubes used to introduce and withdraw fluids. If anything, these definitions serve to reinforce the proposition that some needles may be used as pipetting tips, some pipetting tips may be used as needles, and that needles and pipetting tips may be used in combination (i.e. attaching a needle to the pipetting tip or the pipette body).

(b) The septum in Barbera-Guillem is preslit and not a rubber seal.

In response, please consider the following remarks.

Barbera-Guillem teaches that a preslit septum is just one of many possible types of rubber seals. It is reiterated that Barbera-Guillem teaches in paragraphs [0058] and [0225]-[0228] that needles provided on the end of a pipetting tool are readily used to pierce any rubber seal, including those that are not preslit.

(c) Pipetting operations are not possible with the device of Tanaami. Pipetting operations require removal of the rubber plug which imply removal of the mandatory negative pressure applied inside the device.

In response, please consider the following remarks.

The proposed combination of Tanaami with Barbera-Guillem does not destroy the mode of operation set forth by Tanaami. Tanaami already discloses the use of a needle to piece a rubber seal and deliver fluids to the tube. Barbera-Guillem is merely cited as evidence that it would be obvious to attach the same Tanaami needle to a pipetting tool to allow for the controlled addition of a precise amount of reagent through the needle. The rubber seal would not be removed, and once fluids are added to the interior of the tube, they would be acted on by the same negative pressure forces to encourage flow across the length of the tube. An appropriately formed, "needle-like" pipetting tip itself could be pushed through the rubber seal, or the Tanaami needle could simply be attached to the pipette. Either way, the combination comprises an opening adapted for receiving a pipetting tip.

(d) Lehmann does not disclose a tubular body.

In response, please consider the following remarks.

It is agreed that Lehmann discloses an apparatus that appears to be a flat cartridge. However, it is noted that Lehmann is not relied upon for teaching a reaction vessel having a tubular body. Tanaami expressly discloses the use of a reaction tube wherein a chip shaped carrier is fit to match the contour of the tube inner wall.

(e) The pre-processing block of Tanaami would be damaged if pipetting operations were conducted in the processing chamber.

In response, please consider the following remarks.

Tanaami discloses a system in which the rubber plug (13) is penetrated by a needle in order to deliver fluid to a holding part (14) without damaging the pre processing part (15). The use of a pipetting device to puncture the rubber plug or, alternatively, a needle attached to a pipetting device to puncture the rubber plug would likewise not damage the pre processing part because fluid would be added to the holding part – not the pre processing part. The pipetting tip would simply be moved into the holding part, and would not interfere with or damage the pre processing part. Accordingly, the combination of Tanaami and Barbera-Guillem would not change the principle of operation of Tanaami, and would only involving use a pipetting tip to deliver fluid rather than a needle.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN A. BOWERS whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 7 AM to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571) 272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nathan A Bowers/
Examiner, Art Unit 1797